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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

May 7, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 21

David Ohrt, M.D.
Medical Director
St. Mary's Healthcare Center
803 East Dakota
Pierre, South Dakota 57501

Dear Dr. Ohrt:

During an inspection of St. Mary's Healthcare blood bank located at Pierre, SD on March 30-31, 1998, pursuant to a request from our Center for Biologics Evaluation and Research to investigate a report of a transfusion associated fatality, our investigator documented violations of Section 501(a)(2)B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680, as follows:

> Failure to follow written SOPs used for collecting and identifying the blood samples of recipients to ensure positive identification, [21 CFR 606.151(a)] in that personnel did not follow written SOPs for the crossmatch policy confirming the identification of the blood samples before beginning the procedure (FDA-483 item #1) and did not positively compare the PID number on the Lab Report with that on the Blood Bank II form (FDA-483 item #2);

Failure to identify any unexplained discrepancies during review of records pertinent to the unit before release or distribution [21 CFR 606.100(c)] in that personnel failed to identify the discrepancy between the hand-written and computer generated identification numbers on the Blood Bank II record (FDA-483 item #5);

Failure to maintain written Standard Operating Procedures which include the precautions to be taken to identify accurately the recipient blood samples and crossmatched donor units [21 CFR 606.140(c)] in that written procedures do not clearly define the terms "computer ID number," "patient number," and "hospital number" so as to identify record entries to be reviewed prior to issue of blood products for transfusion (FDA-483 item #3).

We note that at the close of the inspection your firm made a verbal commitment and had begun to take measures to address the concerns referenced on the FDA-483 including the use of a new blood sign-out sheet (which incorporates the patient identification number), training of personnel, and the use of a unique identification system for the blood samples.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct theses deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of Compliance Officer Howard E. Manresa at the address on this letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

HEM/ccl

xc: James Russell, CEO
Chief Executive Officer
St. Mary's Healthcare Center
803 East Dakota
Pierre, SD 57501